

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Pamela M. Drake et al.
Application No. : 10/763,570
Filed : January 23, 2004
Confirmation No. : 4880
For : COMPOSITIONS AND METHODS FOR RESTORING
BACTERIAL FLORA

Examiner : Lora E. Barnhart
Art Unit : 1651
Docket No. : 340082.401
Date : _____

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PAMELA M DRAKE

PURSUANT TO 37 CFR § 1.132

Commissioner for Patents:

I, **Pamela M. Drake**, declare as follows:

1. I, **Pamela M. Drake**, am familiar with the subject matter disclosed and claimed in U.S. Patent Application No. 10/763,570, filed January 23, 2004, and titled "COMPOSITIONS AND METHODS FOR RESTORING BACTERIAL FLORA" ("the '570 Application").
2. I am **President of Flora Technology, Inc.**, located in **Aberdeen, Washington, United States**.
3. My educational and professional background includes is attached.

4. I have reviewed the Office Action dated August 31, 2006, including the Examiner's rejections and cited references.
5. I am familiar with the contents of the '570 Application.
6. Routine antibiotic use contributes to significant health problems related to the disruption of intestinal flora. Examples of some of the significant health problems associated with routine antibiotic use include the growth of opportunistic, anti-microbial resistant infections, such as Methicillin Resistant *Staphylococcus aureus* (MRSA), *E. coli*, *Clostridium difficile*, and fungal infections. Medical Practitioners have seen an increase in cases of resistant infections and other complications following antibiotic use.
7. The cost of treating patients with antibiotics often increases because the disruption of the gut flora may create additional complications requiring continual medical intervention. The solution lies in re-establishing healthy intestinal flora, which may be accomplished by administering a probiotic alongside the anti-microbial.
8. Probiotics are live, beneficial microbes that protect their host and prevent disease. The present standard of care relating to antibiotic use does not include the concurrent use of probiotics. Instead, probiotics are usually provided after an opportunistic infection has already arisen.
9. Probiotics, if suggested or prescribed by a physician, are presently available primarily as a separate purchase.
10. Most insurance companies do *not* cover separate probiotic purchases. Patients must therefore pay for probiotic supplements separately, and at the patient's own expense.
11. There exists both a critical and a long-felt need for a product that effectively combines both anti-microbial and probiotic treatments in a single kit, and which may be sold to the patient as a single prescription.
12. I am familiar with the contents of U.S. Patent No. 6,645,506 ("the 'Farmer' patent").

13. The "Farmer" patent merely discloses the use of *topical* probiotic compositions, which are not useful for treating anti-microbial disruptions of the intestinal flora.
14. There is a critical and long-felt need for an anti-microbial/probiotic kit that is not exclusively topical, and which may be used to treat disruptions of the intestinal flora.
15. The enclosed letters offer evidence that medical practitioners indicate that their patients would benefit from a kit that combines both a probiotic and anti-microbial in a single prescription, and that they would routinely prescribe such a kit if it were available.
16. The enclosed letters were written by primary care medical practitioners in support of anti-microbial/probiotic kits that are presently under development by Flora Technologies, and include letters from Roy Ozanne, M.D., H.M.D., Colette M. Kato, D.O., Patrician Sylwester, M.D., Karolina Wilczynaka-Oberc, M.D., Patrick Litster, M.P.A.S., PA-C, Ann Tosomeen, M.D., Maribeth T. Duffy, M.D., and Pamela J. Baxter, PA-C, R.T.R.M.

I hereby declare that all statements made herein are, to my own knowledge, true and that all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the captioned patent application or any patent issued therefrom.

7/23/07
Date

Pamela J. Baxter
Name

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Pamela M. Drake

Education and Professional Background

1975 –1976 Northern Montana College Havre, MT
Licensed Practical Nursing Program

1976-1977 Sacred Heart Hospital Spokane , WA
Nursing - Employed in the Neuro Unit

1982-1983 Dr. Stan Autry ND Lewiston, ID
Natural Health and Colon Therapy Training and Certification

1983 Toxygen Corporation San Francisco, CA
Representative and Co-author

- Represented Toxygen Colon Hydrotherapy Equipment at a Natural Health Conference and helped write a colon therapy protocol manual for Toxygen Hydrotherapy Machine and Florida Colon Therapy Association.

1985-1987 Dr. Hastings ND Olympia, WA
Colon Therapist and Lecturer on Colon Health

1982-Present Self-employed Aberdeen, WA
Pam Drake Natural Health Consulting

- Independent natural health researcher and Nutritional Consultant/Nutritional Therapy Practitioner. Located in Aberdeen, WA. Private and Physician referred clientele. Individualized natural health programs developed for each client with emphasis on indigenous diets and lifestyles working closely with their Physicians when referred.

1995-2003 Lecturer Statewide
Developer of Food for Thought Workshops

- Lectured at schools, churches and local community groups regarding natural health and cooking skills. Workshops included in-home presentations and demos on whole foods.

1995-2003 Catering Aberdeen, WA

Whole Foods Catering

- Community whole food catering for non-profit and private groups.

1997-Present Flora Technology Corporation Aberdeen, WA

Founder and President

- Flora Technology was formed in 1997 and in 2000 became a for-profit corporation dedicated to "Raising the Standard of Practice" regarding the antibiotic protocol.

2000-2002 Rose Espresso Plus Aberdeen, WA

Whole Food Consultant

- Created a whole foods menu and educated owner of a local restaurant in the preparation of specialty breads, salads and soups.

2001-2002 South Puget Sound Community College Olympia, WA

Nutritional Therapist Training Program

- Completed 110 hours nutritional training to certify as a Nutritional Therapist with the Nutritional Therapy Association.

2000-Present Weston A. Price Foundation Aberdeen, WA

Establisher and President

- Established the first Washington State Chapter of the Weston A. Price Foundation- a whole foods education foundation.
- Helped establish and develop raw milk distribution and whole foods network for Grays Harbor area
- Head of Co-op drop sight for Azure Standard (Oregon State) a natural foods distribution company. Organizes and distributes products received monthly and manages payment received for the goods.

2004-Present Community Lecturer on Natural Health

Instructor

- Commissioned to teach natural health cooking and lecture on healthy lifestyles to various local organizations. Some of these lectures included: Nutrient Dense Cooking on a budget, Diabetic Cookery, and Special Nutrition needs in Seniors to name a few.

2005 Traditional Foods Diets & Lifestyles Conference Ocean Shores, WA

Co-Organizer

- National four-day Conference on food, soil and environmental chemical connections to Health with multiple world-renowned professional presenters from many fields in relationship to health and wellness.

2005-Present Shoalwater Bay Wellness Center Tokeland, WA

Nutritionist

- Providing consultations to tribal and community members for nutritional support upon referral by client's physicians. Co-administrate basic food & nutrition education programs and provides nutrition consultation for the diabetic educator.

**Natural Health
Publications**

Developed "Food For Thought Workshops", a series of materials on natural health education.

Developed power-point educational presentation "Foundations In Whole Foods" Part I and Part II. (A 24 hour lecture series on whole food and health and cooking demonstration.) This series has been adopted by the Nutritional Therapy Association as an instructional tool in 7 different colleges as part of their continuing education for their certification program.